

Significant Legislative Rule Analysis

For Rules Concerning Animal Control Agencies and Humane Societies use of Legend Drugs for Euthanasia

Chapter 246-886 WAC and WAC 246-887-050, 060, and 070.

Section 1. What is the scope of the rule?

The Board of Pharmacy (board) has proposed changes to the rules that apply to animal control agencies and humane societies that hold a certification for sodium pentobarbital. The rules update current requirements for training personnel, and the administration and recordkeeping of legend drugs and sodium pentobarbital. The proposed rules standardize training and recordkeeping requirements for sodium pentobarbital, a controlled substance, mirroring those for approved legend drugs used for pre-euthanasia sedation. In addition, the board proposes to consolidate all rules regarding the administration and recordkeeping for sodium pentobarbital under chapter 246-886 WAC.

Section 2. What are the general goals and specific objectives of the proposed rule's authorizing statute?

RCW 69.41.080 and RCW 69.50.310 authorize the board to adopt rules as deems necessary to ensure strict compliance with the statute.

The statutes' objective is to promote public health of the citizens of Washington by making certain that individuals with adequate knowledge and training of the potential hazards administer drugs used for pre-euthanasia sedation and animal euthanasia.

The board has determined that specific practice standards are needed to meet this objective and protect the public from diversion and misuse of drugs through storage, recordkeeping, and inventory controls.

Section 3. What is the justification for the proposed rule package?

Rules are needed in order to establish enforceable standards for training, administration, storage, and recordkeeping. The rules will establish minimum training parameters to ensure individuals are adequately trained in the proper techniques and understanding of the potential hazards associated in the administration of approved legend drugs and sodium pentobarbital for purposes of animal euthanasia.

Section 4. What are the costs and benefits of each rule included in the rules package? What is the total probable cost and total probable benefit of the rule package?

1. Identification of total number of rules in package: 15

WAC 246-886-001 Purpose
WAC 246-886-010 Definitions.

WAC 246-886-020 Registration.
WAC 246-886-030 Approved legend drugs.
WAC 246-886-035 Sodium pentobarbital – Approved controlled substance.
WAC 246-886-040 Training of personnel.
WAC 246-886-060 Responsible individuals.
WAC 246-886-070 Notification
WAC 246-886-080 Recordkeeping and Reports.
WAC 246-886-090 Drug storage and field use.
WAC 246-886-100 Violation.
WAC 246-886-180 Approved legend drugs

WAC 246-887-050 Sodium pentobarbital for animal euthanasia
WAC 246-887-060 Sodium pentobarbital administration.
WAC 246-887-070 Sodium pentobarbital administration.

2. Non-Significant Rule Identification Table

Table: Non-Significant Rule Identification

WAC Section	Section Title	Purpose	Exemption
246-886-001	Purpose	Updates rule language by incorporating controlled substances used for euthanasia as formerly address in repealed rule section.	Intent of chapter
246-886-010	Definitions	Clarifies language without changing its effect.) The defined terms clarify language of the rule without changing its effect.
246-886-035	Sodium pentobarbital – Humane society and animal control agency	Language is being moved from WAC 246-887-050 to consolidate standards under Chapter 246-886 WAC	There are no new requirements.
246-886-060	Responsible individuals - Humane society and animal control agency	Removed reference to sections repealed from Chapter 246-887 WAC.	Makes a grammatical change only without changing the intent.
246-886-090	Drug storage and field use.	Language is being moved from WAC 246-887-050 to consolidate standards under Chapter 246-886 WAC	There are no new requirements.
246-886-100	Violation - Humane society and animal control agency	Clarifies language by adding reference to RCW 69.50.310 the authorizing statute for use of sodium pentobarbital.	Incorporates by reference a state law without changing the effect.
WAC Section	Section Title	Purpose	Exemption
246-886-180	Approved legend drugs – Chemical capture program	Adds a new section listing drugs authorized for use by the Washington State Department of Fish and Wildlife (WDFW) Chemical Capture programs. This language was originally listed under WAC 246-886-030.	There are no new requirements.
Repealed Sections			
246-886-070	Notification	Language moved to WAC 246-886-080.	No change in requirements.

246-887-050	Sodium pentobarbital for animal euthanasia	Language moved to WAC 246-886-035.	No change in requirements.
246-887-060	Sodium pentobarbital administration.	Language moved to WAC 246-886-020 and 080.	No change in requirements.
246-887-070	Sodium pentobarbital records and reports	Language moved to WAC 246-886-020, and 080.	No change in requirements.

3. Significant Rule Analysis

A. WAC 246-886-020 Registration.

Rule Overview. The proposed rule includes existing rule language from WAC 246-887-060 which required policies and procedures to be filed with the board at the time the initial application of registration as an animal control agency or humane society. The proposed rule goes further by providing specific factors or standards that must be address in the policies and procedures to demonstrate adequate knowledge for administration of approved drugs and a system for regulating appropriate drug storage, inventory controls and recordkeeping.

Rule Cost/Benefit Analysis – The proposed rule does not add a new requirement to those entities seeking registration. The rule defines the key elements needed in the policies and procedures and is consistent with the standards established in chapter 246-886 WAC and RCW 69.41.080. In 2009, the Board of Pharmacy approved model policies and procedures for animal control agencies and humane societies as guidance to assist those needing to comply. The amendment to the rule does not create a burden or additional costs since the requirement for policies and procedures already exist. The rule will benefit the registered entity in developing appropriate policies and procedures to meet the objectives of the registration by ensuring authorized staff are adequately trained and processes for drug accountability are established.

B. WAC 246-886-030 Approved legend drugs.

Rule Overview. The proposed rule adds Dexemetomidine, and Medetomidine to the list of approved legend drugs and makes technical correction by removing Ketamine.

The board asked for input regarding appropriateness of the current list of approved legend drugs used for sedation of animals prior to euthanasia. They consulted with the Veterinary Board of Governors and stakeholders that identified Dexemetomidine and Medetomidine as effective options for sedation of animals that do not react well to the other drugs on the list.

In 1999, the federal Drug Enforcement Administration reclassified Ketamine as a Schedule III controlled substance, hence it is being removed from the list. Sodium pentobarbital is the only controlled substance authorized by the law that the registration issued to humane societies and animal control agencies are authorized to purchase, possess, and administer.

Rule Cost/Benefit Analysis – The rule amendments add additional legend/prescription drugs to the list of drugs approved for use by registered humane societies and animal control agencies for pre-euthanasia sedation. The proposed rule does not impose costs to a registered entity, but provides the entity additional tools for authorized personnel to use to adequately sedate an animal prior to euthanasia.

C. WAC 246-886-040 Training of personnel.

Rule Overview. The proposed rule adds to the list of training elements in a board-approved or substantially equivalent euthanasia training program. The programs must provide an opportunity for an individual to gain adequate knowledge of the potential hazards and proper techniques to be used in the administration of approved legend drugs and sodium pentobarbital. The proposed amendment adds:

- Methods of euthanasia;
- Routes of drug administration;
- Use of sedatives;
- Drug dosing;
- Use of restraints;
- Process and verification of death; and
- Applicable federal and state laws and rule.

Rule Cost/Benefit Analysis – Incorporating applicable Washington State laws and rules may require additional hours of research for the program developer (veterinarian) seeking board approval. The board received input from practicing veterinarians on the impact of the proposed changes to the training program. Based on this input, the board's assumption is that veterinarians will spend approximately two additional hours to amend their training program to include these additional elements at an estimated cost of \$89.42 (2 hours at \$44.71¹ per hour).

The benefit of this rule is to clarify the board's expectation regarding training curriculum to those interested in seeking board approval. The training topics will help authorized personnel of registered entities to meet the qualifications to demonstrate adequate knowledge of the potential hazards involved in and the proper techniques to be used in the administering the drugs.

D. WAC 246-886-080 Recordkeeping and reports - Humane society and animal control agency

Rule Overview – The proposed rule establishes the elements required in a drug logbook to account for the use and wastage of approved legend drugs and sodium pentobarbital. The drug logbook elements are consistent with standards established by the Humane Society of the United States (HSUS). HSUS is a provider of board-approved euthanasia training and training manual. This is also consistent with federal Drug Enforcement Administration record requirements cited in the code of federal regulations 21CFR1304 Records and Reports of Registrants.

Drug logbook must include:

- (a) Date and time of administration;
- (b) Route of administration;
- (c) Identification number or other identifier assigned to the animal;
- (d) Estimated weight of the animal;
- (e) Estimated age and breed of the animal;

¹ The average hourly earnings reported by the United States Department of Labor, Bureau of Labor Statistics for a veterinarian is \$44.71 (29-1131).]

- (f) Name of drug used;
- (g) Dose of drug administered;
- (h) Amount of drug wasted; and
- (i) Initials of primary person administering the drug.

Note: items (b), (d), and (e) may be omitted from the drug logbook if recorded in other records cross-reference by the animal identification number.

The proposed rule also incorporates the language in repealed section WAC 246-886-070 and WAC 246-887-060 consolidating recordkeeping requirements and authorized personnel.

Rule Cost/Benefit Analysis – Registered humane societies and animal control agencies already have a mechanism in place to record drug usage. The additional required elements will not create a burden and would benefit the agency in accounting for drug inventory and deter diversion.

Rule Package Cost-Benefit Conclusion

As the analysis above indicates, the rules create standards for a comprehensive training curriculum for euthanasia training programs seeking approval by the board to demonstrate adequate knowledge to possess, and administer drugs necessary to sedate and euthanize injured, sick, homeless or unwanted domestic pets, and domestic or wild animals.

Although these proposed rules require a nominal additional burden on registered entities or those entities seeking registration, the rule's benefit of clarifying and standardizing the requirements for storage, inventory controls, administration, and recordkeeping standards for sodium pentobarbital and approved legend drug and other records maintained by the registered entity are greater than the cost of implementing the proposed changes. Therefore the total probable benefits of the rule exceed the total probable costs.

Section 5. What alternative versions of the rule did we consider? Is the proposed rule the least burdensome approach?

Descriptions of alternatives considered

Alternative version: WAC 246-866-080 Recordkeeping and reports – Humane societies and animal control agencies. States in part...The drug logbook shall be in sufficient detail to perform an audit and must include... (d) Animal weight; (i) initials of all involved in the process; (j) Conscious state of the animal.

Stakeholders had concerns that the additional detail proposed for documentation in the logbook was neither pertinent nor practical – specifically weight and whether the animal was conscious or not. Others felt the additional recordkeeping elements included some of the same information already recorded in other agency records requiring them to duplicate entries.

Compared to the alternative version, the proposed rule is less burdensome for those required to comply. The proposed rule requires an estimated weight of the animal; initials only of those persons that administered the drugs; and removed documentation of the animal's conscious state. *Note:* Estimating the weight of the animal is necessary to determine the appropriate dosing.

Section 6. Did you determine that the rule does not require anyone to take an action that violates another federal or state law?

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

Section 7. Did we determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless the difference is required in federal or state law?

The Department of Health and the board has determined that the rule does not impose more stringent performance requirements on private entities than on public entities.

Section 8. Did you determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, did we determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary?

The rule does not differ from any applicable federal regulation or statute.

Section 9. Did we demonstrate that the rule has been coordinated, to the maximum extent possible, with other federal, state, and local laws applicable to the same activity or subject matter?

There are no other applicable laws.